Remarks

Claims 1-17, 25-34, and 36-37 are pending in this application. Claims 1, 15, and 32 have been amended. Claims 38-47 have been added to further define what is regarded as the Applicant's invention. The amendments made herein to the claims do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the instant specification.

Claim Rejections under 35 USC 102

In the Office Action, the Examiner has rejected claims 1, 15 and 32 under 35 U.S.C. §102(b) as unpatentable over U.S. Patent 3,073,306 to Linder (hereinafter "Linder") or U.S. Patent 5,873,856 to Hjertman et al. (hereinafter "Hjertman") or U.S. Patent 4,373,526 to Kling (hereinafter "Kling").

In the Office Action when referencing the disclosure of Linder, the examiner states (emphasis added):

> *"The Structural relationship between the outer tube (80) and the extension sleeve (10) allows the operator of this medical device to adjust the exposed length of the needle as it deploys through extension sleeve (10)."*

This would imply that there is a movable relationship between the limiter of Linder and the device. It is precisely this adjustability of Linder that differentiates Linder from the Applicant's claimed invention as exemplified by the currently amended claims. The adjustability of Linder does not allow for precise setting of injection depth. In contrast, Claims 1, 15, and 32, as now amended, require a fixed relationship between the limiter and the device. The fixed relationship, as now exemplified by the currently amended claims, has the additional benefit of allowing the manufacturer of the device to set the preselected insertion depth with a high degree of certainty, which is desirable for achieving a proper intradermal delivery. The manufacturer is

thusly able to eliminate the insertion depth variations due to such factors as manufacturing assembly tolerances, user variation, and part dimensional fluctuations.

Hjertman discloses a limited depth penetration needle housing that facilitates "injection, especially subcutaneous injection." See, e.g., column 1, lines 1-2 of Hjertman. The device includes a sleeve (1) that is displaceable rearwards against the force of a spring during an injection. After the injection is complete, the spring causes the sleeve (1) to return to a starting position. See, e.g., FIGS. 1 and 2. Thus, Hjertman only discloses a movable limiter.

Similarly, Kling discloses a device having a movable sleeve that limits the injection depth of a needle to the intramuscular or subcutaneous areas of the skin. Thus, Kling only discloses a movable limiter.

In summary, even if the Linder, Hjertman, and/or Kling devices performed all the functions recited in Claims 1,15 and 32 the devices of Linder, Hjertman, and/or Kling cannot anticipate the claim if there is any structural difference. (See MPEP § 2114 and *In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999)*). Furthermore, to support a rejection of a claim under 35 U.S.C. § 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. The devices of Linder, Hjertman, and/or Kling all have movable limiters. Thus, Applicant submits that currently amended Claims 1, 15, and 32 are allowable over Linder, Hjertman, and/or Kling since the structure of Linder, Hjertman, and/or Kling is different from the Applicant's claimed invention.

Claim Rejections under 35 USC 103

In the Office Action, the Examiner has rejected claims 2-14, 16-17, 25-31, 33-34 and 36-37 under 35 U.S.C. §103(a) as unpatentable over Linder, Hjertman, and/or Kling. Thus, applicant respectfully submits that the shortcomings of Hjertman, Kling and Linder individually, are not overcome by the teachings or suggestions of combinations or modifications of the three cited references. The Examiner's proposed modifications and/or combinations of Linder, Hjertman and Kling teaches an injection device having a movable limiter that controls the depth of injection of the needle to the screw-adjustable (Linder) or subcutaneous (Hjertman and Kling) or intramuscular (Kling) areas of the skin. Applicant respectfully submits that such teachings do

not render the claims of the present application obvious. Applicant's invention is directed to an intradermal delivery device for making intradermal injections that comprises, *inter alia*, a non-movable limiter that limits penetration of the needle to the dermis layer of the skin. Applicant respectfully submits that none of the cited art references relied upon by the Examiner in the Office Action, nor any other prior art references of record in the present application, teach or suggest such a device.

Applicant further respectfully submits that the Examiner has not made the required *prima facie* case of obviousness for claims 2-14, 16-17, 25-31, 33-34 and 36-37. See, e.g., MPEP §2142, 2143 et seq. Specifically, Applicant respectfully submits as discussed previously, that the Examiner has failed to show that the references teach or suggest all the claim limitations. The Examiner states that "*modifying any of the cited patents to have a needle penetration depth in the range of 0.5 mm to 3 mm would have been considered an obvious design alternative.*" However, as noted above, the disclosure of Linder, Hjertman, and Kling are specifically directed to movable limiters. Applicant submits that an obvious design choice for needle penetration depths according to the reference cited must provide for a subcutaneous or intramuscular injection utilizing a movable limiter. As noted above, injections in the range recited by applicants claims (e.g., equal to approximately 0.5 mm to approximately 3.0 mm) provide only for intradermal injections. All three references are silent with regard to the desirability or requirements of intradermal injections. Applicant respectfully submits that, based on the teachings of Linder, Hjertman and/or Kling as considered alone or in combination with each other (or with any other cited reference in the present application), a person of ordinary skill in the art would not conclude that a predetermined needle penetration range including 0.5 mm to approximately 3.0 mm would be an obvious design choice for any of the devices disclosed by Linder, Hjertman and Kling, as such a range would not provide for subcutaneous injections with a movable limiter, as is clearly the intent of the cited references.

Furthermore, since the disclosure of Linder, Hjertman, and Kling are specifically directed to movable limiters, they cannot teach or suggest the limitations of Applicant's Claims 2 or 38, which requires an integrally formed limiter, which would be contrary to the operation of the devices of Linder, Hjertman, and Kling. Moreover, the movable limiters as disclosed by Linder,

Hjertman, and Kling are spaced from the needle with sufficient spacing to allow movement of the limiter with respect to the needle, thus none of the reference teach or suggest Applicant's limitation of a limiter proximate to the needle or having a central opening only slightly larger than the needle. Applicant respectfully submits that none of the cited references relied upon by the Examiner in the Office Action, nor any other prior art references of record in the present application, teach or suggest such limitations.

Non-Statutory Double Patenting Rejection

In the Office Action, the Examiner has rejected Claims 1-17, 25-34, and 36-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,494,865. In response thereto, Applicant proposes that a Terminal Disclaimer in accord with 37 CFR 1.321(c) for U.S. Patent 6,494,865 will be filed at which time allowable subject matter is identified.

New Claims

New claims 38-47 have been added to further define aspects of the invention, which are fully supported by the instant specification. Accordingly, no new matter has been added. New independent claim 38 has similar elements and structure as original Claim 15 but in addition recites the limitations of a glass container and an integrally formed limiter. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest a device according to the present invention. Without discussing each in detail, it will be appreciated that the claims depending from Claim 38 recite additional features that are not taught or suggested by the prior art.

Conclusion

In view of the Amendments submitted, Disclaimer filed herein and the Remarks above, Applicant respectfully submits that Claims 1-17, 25-34, and 36-47 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider his rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, Extension of Time, Petition to Revive, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

By: _____

Dated: July 7, 2005.

Robert E. West
Reg. No. 48,030
Agent for Applicants
(201) 847-6782

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880
Fax : 201-847-5377

::ODMA\PCDOCS\DM5105LIBRARY\95065\1